

### REMARKS

Claims 1, 11, 12, 14, 15, 18, 22, 25, 29 and 33 are amended. Claims 2, 13, 20, 21, 23, 27 and 28 are cancelled. Claims 1, 3-12, 14-19, 22, 24-26 and 29-33 will be pending upon entry of this amendment.

#### ***Declarations of Commercial Success and Satisfaction of Long-Felt Need***

As evidenced of the patentability of the claimed invention, applicant submits the accompanying declarations of Todd White, a registered nurse at St. Francis Hospital who has experience using compression sleeves, including prior art sleeves and the commercial version of the sleeve of this invention (sold under the trademark KAMBIA), and Jeffrey Wyrzten, Global Product Manager, Compression, of the company selling the commercial version of the sleeve of this invention.

In his declaration, Mr. White states that compression sleeves are often used to protect the limbs (e.g., leg) of a patient during surgery. Thigh-length sleeves (sleeves extending from the ankle area past the knee to the upper thigh) are typically used during surgery because of their ability to fully cover the leg for protection. Prior to the KAMBIA sleeve, compression sleeves were not capable of being modified from the thigh-length configuration to the smaller knee-length size (sleeves extending from the ankle area to just below the knee). Accordingly, after surgery was complete, the clinician was forced to either leave the thigh-length sleeve on which can be uncomfortable, or completely replace the thigh-length sleeve with a separate knee-length sleeve which is costly.

It has been Mr. White's experience that the KAMBIA sleeves provide easy conversion from the thigh-length to the knee-length configuration. He likes the KAMBIA sleeve because you get optimum protection during surgery yet still have the ability to rip the sleeve down to the knee-length sleeve to improve comfort post operation. This convenient tear-away feature provides the long overdue advantage of being able to use a single sleeve during and after surgery without compromising protection or comfort. Mr. White states, without qualification, that he would recommend to the board at Saint Francis that they purchase the KAMBIA sleeves because the sleeve's versatility, ease of use and cost saving potential.

In his declaration, Mr. Wyrzten states that the KAMBIA sleeve is a commercially successful product. The product was launched globally by Covidien in 2005, and sales have enjoyed a rapid rate of growth, as exemplified by the numbers on the spreadsheet attached to Mr. Wyrzten's declaration. According to Mr. Wyrzten, the sales growth for the KAMBIA product has been greater than would normally be expected for comparable products sold by Covidien. Further, based on customer feedback, including the accompanying declaration from nurse Todd White, Mr. Wyrzten believes the commercial success of the KAMBIA sleeve is due its tear-away feature allowing the sleeve to be readily converted from a thigh-length to a knee-length configuration. The tear-away feature improves the sleeve's versatility, ease of use, and cost saving potential.

Clearly, the attached declarations of Mr. White and Mr. Wyrzten establish that the KAMBIA sleeve of the present invention is commercially successful; that the commercial success is due to applicant's claimed tear-away feature; and that the KAMBIA sleeve satisfies a long-felt need in the industry for a sleeve that can be used both during and after surgery without compromising protection or comfort. These factors strongly support the non-obviousness of applicant's claimed invention.

### ***Claim Rejections - 35 USC §103***

#### **Claims 1, 3-12, 14, 18-19, 22, and 24-26**

Claims 1, 3-12, 14, 18-19, 22, and 24-26 are rejected as unpatentable over Dye (5,795,312) in view of Arkans (6,358,219).

Claim 1 is amended to state, among other things, that applicants' connector communicates with the first, second, and third expandable chambers via a tubular pathway comprising first tubing extending from the connector and fluidly connecting to the first expandable chamber, second tubing extending from the connector and fluidly connecting to the second expandable chamber, and third tubing extending from the connector and fluidly connecting to the third expandable chamber. In other words, the first, second and third tubing extends from the same connector to respective expandable chambers. The claim is also amended to state that the first tubing extends from the connector across the perforations to the first expandable chamber. The prior art fails to show or suggest this feature.

Dye discloses a compression sleeve having expandable chambers, but it fails to show or suggest applicants' claimed perforations.

Arkans '219 discloses a compression device having foot and calf sections which may be separated by cutting through an attachment 38 (Fig. 1; col. 6, lines 59-64). The inflatable bladders in the Arkans device are inflated using separate fittings 40 (Fig. 2) and 56 (Fig. 3) which are not shown as being connected in any way.

The examiner contends it would have been obvious in view of Arkans '219 to completely remove one portion of the Dye sleeve from another portion of the sleeve. Applicants respectfully disagree. In applicants' claimed design, the same connector connects the source of pressurized fluid (e.g., a controller) to the first, second, and third tubing leading to respective first, second, and third expandable chambers, and the first tubing extends from the connector across the perforations to the first expandable chamber. This arrangement is not disclosed or suggested by the prior art. On the contrary, the skilled person would avoid cutting or otherwise removing one portion of the sleeve from another at a location which would also apparently require cutting or otherwise severing the first tubing, because cutting or otherwise severing the first tubing would interfere with the flow of pressurized fluid through the common connector to the other (second and third) expandable chambers and thus prevent continued sequential compression vascular therapy after separation of one portion of the sleeve from another. Specifically, the skilled person would recognize that severance of the sleeve and first tubing at this location (i.e., where first tubing crosses the perforations) would cause uncontrolled loss of fluid through the first tubing, which would typically trigger the source of pressurized fluid (e.g., the controller) to cease further flow of pressurized fluid to the second and third expandable chambers. Accordingly, the skilled person would be led away from a design in which the first tubing extends across the area where the sleeve is to be severed.

Moreover, neither Dye nor Arkans discloses the use of perforations to separate one portion of the compression device from another. The examiner contends that perforations are an obvious equivalent to cutting. Applicants disagree. Perforations permit separation of the two sleeve components along a precise, predetermined, and unchangeable path without the use of a cutting implement. On the other hand, cutting

requires the use of a cutting implement, and the path of the cut can vary (intentionally or unintentionally) from the proper path, which is undesirable. Moreover, the skilled person would not be inclined to use perforations extending completely across a compression sleeve used on a limb, as claimed by applicants, because repeated articulation of the limb could cause unintended separation of the sleeve along a weakened line created by the perforations

In view of the foregoing, amended claim 1 is submitted to be allowable.

Claims 3-12 and 14 depend (either directly or indirectly) from claim 1 and are believed to be allowable for at least the same reasons as claim 1.

Further, claim 11 states that applicants' compression apparatus comprises a quick disconnect port permitting easy removal of the first tubing from the connector when the first portion of the sleeve is removed from the second portion of the sleeve. The second tubing and the third tubing remain attached to the connector when the first portion of the sleeve is removed from the second portion of the sleeve. This feature is neither shown nor suggested by the prior art, including the Dye and Arkans '219 patents. The examiner contends that Arkans 6,062,244 shows a similar feature. Applicants disagree. Arkans '244 discloses an arrangement in which the upstream and downstream connector parts 42, 44 are either connected to permit flow of pressurized fluid through both lines 32a, 32b to the compression device or disconnected to prevent flow through both lines 32a, 32b to the compression device. The connector parts and fluid flow lines cannot be manipulated to allow one line to be disconnected to prevent (or inhibit) flow to one portion of the compression device while at the same time permitting another line or lines to remain attached to permit flow to another portion or portions of the compression device, as claimed by applicants. Accordingly, claim 11 is allowable for this additional reason.

Claim 12 depends from claim 11 and further states that the connector comprises a valve for partially closing the quick disconnect port when the first tubing is removed from the connector such that fluid from the pressurized fluid source continues to flow from the port and the sequential compression vascular therapy is able to continue without interruption. Applicants' claimed partial-closure feature is advantageous because it allows continued flow through the port vacated by the first tubing to maintain continuity with the pressurized fluid source so that vascular therapy can continue without

interruption after the first portion of the sleeve is removed by tearing along the perforations. In this regard, feedback information to the controller is necessary to achieve proper operation. If a portion of the sleeve is removed, this feedback is interrupted and would normally cause the controller to discontinue operation. However, when the sleeve is equipped with the valve connector of claim 12, pressurized fluid continues to flow through the fluid port even after a portion of the sleeve is torn away and the associated tubing is disconnected from the fluid port of the connector. This continued flow simulates the flow characteristics prior to such disconnection so that the controller continues to operate as if the disconnection had not occurred. (For further details of this valve connection, see page 8, lines 15-21, and page 12, lines 6-15 of the present application. See also Application Ser. No. 10/784,639, published August 25, 2005 as Publication No. 2005/01842645, incorporated by reference in this application).

There is no disclosure or suggestion of applicants' partial closure feature in the prior art cited by the examiner. It will be noted in this regard that disconnection of the connector parts 42, 44 in the '244 Arkans patents results in complete blockage of fluid through the connector parts and fluid flow lines. (See col. 5, lines 46-49.) Partial flow is not permitted. Accordingly, claim 12 is allowable for this additional reason.

Claim 14 depends from claim 12 and is allowable for the same reasons as claim 12. Further, claim 14 states that the first and second portions of the sleeve are connected by a flexible section of reduced width having a knee opening therein, and that the perforations extend across the flexible section at a location below the knee opening. Dye discloses a compression sleeve having a knee opening 16, but Dye does not disclose applicants' claimed perforations or where such perforations should be located relative to the knee opening (e.g., above the knee opening, below the knee opening, or at some intermediate location). Applicants' claimed location below the knee opening is particularly advantageous because the amount of scrap remaining on the second portion of the sleeve is minimized after the first portion is torn away.

Claim 18 is amended along the same lines as claim 1 to state that first tubing extends from the connector (which is common to all three tubings) across the perforations to the first inflatable chamber. As explained above in regard to claim 1, the skilled person would avoid cutting or otherwise removing one portion of the sleeve from another

at this location, i.e., at a location which would also require cutting or otherwise severing the first tubing, because cutting or otherwise severing the first tubing would interfere with the flow of pressurized fluid through the common connector to the other (second and third) inflatable chambers and thus prevent continued sequential compression vascular therapy after separation of one portion of the sleeve from another. Thus, amended claim 18 is submitted to be allowable for the same reasons stated above regarding claim 1.

Further, claim 18 states that the first tubing of the tubular pathway is removed from the connector when the first portion of the sleeve is removed from the second portion of the sleeve, and that the second tubing and third tubing remain attached to the connector when the first portion of the sleeve is removed from the second portion of the sleeve to permit sequential inflation of the second and third inflatable chambers after the first portion of the sleeve is removed. This feature is not shown or suggested by the prior art. The examiner contends that Arkans 6,062,244 shows a similar disconnect feature. Applicants disagree. Arkans '244 discloses an arrangement in which the upstream and downstream connector parts 42, 44 are either connected to permit flow of pressurized fluid through both lines 32a, 32b to the compression device or disconnected to prevent flow through both lines 32a, 32b to the compression device. The connector parts and fluid flow lines cannot be manipulated to allow one line to be disconnected to prevent or inhibit flow to one portion of the compression device while at the same time permitting another line or lines to remain attached to permit flow to another portion or portions of the compression device, as claimed by applicants. Accordingly, claim 18 is allowable for this additional reason.

Claim 19 depends from claim 18 and is allowable for at least the same reasons as claim 18.

Claim 22 is amended along the same lines as claim 1 to state that applicants' compression apparatus comprises a connector communicating with inflatable thigh, calf and ankle portions of the sleeve via a tubular pathway comprising first tubing extending from the connector and fluidly connecting to the inflatable thigh portion, second tubing extending from the connector and fluidly connecting to the inflatable calf portion, and third tubing extending from the connector and fluidly connecting to the inflatable ankle

portion. Claim 22 is further amended to state that the first tubing extends from the connector across the perforations to the inflatable thigh portion.

As explained above in regard to claim 1, the skilled person would avoid cutting or otherwise removing the thigh portion of the sleeve from the calf and ankle portions of the sleeve at a location which would also require cutting or otherwise severing the first tubing, because cutting or otherwise severing this tubing would interfere with the flow of pressurized fluid through the common connector to the calf and ankle portions of the sleeve and thus prevent continued sequential compression vascular therapy after removal of the thigh portion.

Thus, amended claim 22 is submitted to be allowable for essentially the same reasons stated above regarding claim 1.

Claim 24 depends from claim 22 and is allowable for at least the same reasons as claim 22. Further, claim 24 states that the first and second portions of the sleeve are connected by a flexible section of reduced width having a knee opening therein, and that the perforations extend across the flexible section at a location below the knee opening. As explained above in regard to claim 14, this feature is patentable over Dye which fails to disclose applicants' claimed perforations or where such perforations should be located relative to the knee opening (e.g., above the knee opening, below the knee opening, or at some intermediate location).

Claim 25 is amended along the same lines as claim 1 to state that a first tubing extends from a connector (which is common to all three tubings) across the perforations to the inflatable thigh portion of the sleeve. As explained above in regard to claims 1 and 18, the skilled person would avoid cutting or otherwise removing one portion of the sleeve from another at this location, i.e., at a location which would also require cutting or otherwise severing the first tubing, because cutting or otherwise severing the first tubing would interfere with the flow of pressurized fluid through the common connector to the other (calf and ankle) portions of the sleeve and thus prevent continued sequential compression vascular therapy after removal of the thigh portion. Thus, amended claim 25 is submitted to be allowable for the same reasons stated above regarding claim 1.

Further, claim 25 states that the first tubing of the tubular pathway is removed from the connector when the thigh portion of the sleeve is removed from the remaining

portions of the sleeve, and that the second tubing and third tubing remain attached to the connector when the thigh portion of the sleeve is removed from the remaining portions of the sleeve to permit sequential inflation of the calf and ankle sleeve portions after the thigh portion of the sleeve is removed. This feature is not shown or suggested by the prior art. The examiner contends that Arkans 6,062,244 shows a similar disconnect feature. Applicants disagree. Arkans '244 discloses an arrangement in which the upstream and downstream connector parts 42, 44 are either connected to permit flow of pressurized fluid through both lines 32a, 32b to the compression device or disconnected to prevent flow through both lines 32a, 32b to the compression device. The connector parts and fluid flow lines cannot be manipulated to allow one line to be disconnected to prevent or inhibit flow to one portion of the compression device while at the same time permitting another line or lines to remain attached to permit flow to another portion or portions of the compression device, as claimed by applicants. Accordingly, claim 25 is allowable for this additional reason.

Claim 26 depends from claim 25 and is allowable for at least the same reasons as claim 25. Further, claim 26 states that the thigh and calf portions of the sleeve are connected by a flexible section of reduced width having a knee opening therein, and that the perforations extend across the flexible section at a location below the knee opening. As explained above in regard to claim 14, this feature is patentable over Dye which fails to disclose applicants' claimed perforations or where such perforations should be located relative to the knee opening (e.g., above the knee opening, below the knee opening, or at some intermediate location).

#### Claims 15-17, and 29-33

Claims 15-17 and 29-33 are rejected as unpatentable over Dye (5,795,312) in view of Arkans (6,358,219), and further in view of Arkans (6,062,244).

Claim 15 is amended along the same lines as claim 1 to state that the first tubing extends across the perforations from a valve connector which is common to the first, second and third tubings. As explained above in regard to claim 1, the skilled person would avoid cutting or otherwise removing one portion of the sleeve from another at this location, i.e., at a location which would also require cutting or otherwise severing the first



tubing, because cutting or otherwise severing the first tubing would interfere with the flow of pressurized fluid through the common valve connector to the other (second and third) inflatable chambers and thus prevent continued sequential compression vascular therapy after separation of one portion of the sleeve from another. Thus, amended claim 15 is submitted to be allowable for essentially the same reasons stated above regarding claim 1.

Further, claim 15 states that the first tubing of the tubular pathway is removable from the valve connector when the thigh portion is removed from the calf portion, and that the second tubing and third tubing remain attached to the valve connector when the thigh portion is removed from the calf portion to permit sequential inflation of said second and third inflatable chambers after said thigh portion of the sleeve is removed. This feature is not shown or suggested by the prior art. The examiner contends that Arkans 6,062,244 shows a similar feature. Applicants disagree. Arkans '244 discloses an arrangement in which the upstream and downstream connector parts 42, 44 are either connected to permit flow of pressurized fluid through both lines 32a, 32b to the compression device or disconnected to prevent flow through both lines 32a, 32b to the compression device. The connector parts and fluid flow lines cannot be manipulated to allow one line to be disconnected to prevent or inhibit flow to one portion of the compression device while at the same time permitting another line or lines to remain attached to permit flow to another portion or portions of the compression device, as claimed by applicants. Accordingly, claim 15 is allowable for this additional reason.

Claims 16 and 17 depend from claim 15 and are allowable for at least the same reasons as claim 15. Further, claim 17 states that the first and second portions of the sleeve are connected by a flexible section of reduced width having a knee opening therein, and that the perforations extend across the flexible section at a location below the knee opening. As explained above in regard to claim 14, this feature is patentable over Dye which fails to disclose applicants' claimed perforations or where such perforations should be located relative to the knee opening (e.g., above the knee opening, below the knee opening, or at some intermediate location).

Claim 29 is directed to a compression apparatus adapted for inflation and deflation by a pressurized fluid source for carrying out sequential compression vascular

therapy on a patient. The apparatus comprises a sleeve configured for disposal about a limb and having boundary edges. The sleeve includes a first portion defining a first expandable chamber and a second portion defining a second expandable chamber and a third expandable chamber, the first, second and third expandable chambers being arranged with respect to each other lengthwise along the sleeve to move blood lengthwise of the limb. The second portion of the sleeve includes a connector for fluidly connecting the pressurized fluid source to the first expandable chamber, the second expandable chamber and the third expandable chamber. The fluid is delivered from the pressurized fluid source to said chambers to carry out vascular therapy. Perforations in the sleeve extend continuously across the sleeve from adjacent one boundary edge of the sleeve to adjacent an opposite boundary edge of the sleeve. The first and second portions of the sleeve are located on opposite sides of the perforations. The sleeve is torn along the perforations to completely remove the first portion of the sleeve from the second portion of the sleeve while leaving the second portion of the sleeve intact for delivery of fluid from the pressurized source to the second and third expandable chambers arranged with respect to each other lengthwise along the sleeve to permit sequential compression vascular therapy on the limb after the first portion of the sleeve is removed. The apparatus also includes first tubing extending from the connector across the perforations and fluidly connecting to the first expandable chamber, second tubing extending from the connector and fluidly connecting to the second expandable chamber, and third tubing extending from the connector and fluidly connecting to the third expandable chamber. The first tubing comprises a quick disconnect port communicating with a fluid port in said connector permitting easy removal of the first tubing from a downstream side of the connector when the first portion of the sleeve is completely removed from the second portion of the sleeve. The second tubing and the third tubing remain attached to the connector when the first portion of the sleeve is removed from the second portion of the sleeve. The connector comprises a valve for partially closing the fluid port when the first tubing is removed from the connector. The fluid continues to flow from the fluid port such that the inflation and deflation by the pressurized fluid source is able to continue without interruption.

Claim 29 is allowable for the same reasons discussed above in regard to claims 1, 11 and 12.

First, in applicants' claimed design, the same connector connects the source of pressurized fluid (e.g., a controller) to the first, second, and third tubing leading to respective first, second, and third expandable chambers, and the first tubing extends across the perforations from the connector to the first expandable chamber. The skilled person would avoid cutting or otherwise removing one portion of the sleeve from another at this location, i.e., at a location which would also require cutting or otherwise severing the first tubing, because cutting or otherwise severing the first tubing would interfere with the flow of pressurized fluid through the common connector to the other (second and third) expandable chambers and thus prevent continued sequential compression vascular therapy after separation of one portion of the sleeve from another. Specifically, the skilled person would recognize that severance of the sleeve and first tubing at this location would cause uncontrolled loss of fluid through the first tubing, which would typically trigger the source of pressurized fluid (e.g., the controller) to cease further flow of pressurized fluid to the second and third expandable chambers. Accordingly, the skilled person would be led away from a design in which the first tubing extends across the area where the sleeve is to be severed.

Second, claim 29 states that applicants' compression apparatus comprises a quick disconnect port permitting easy removal of the first tubing from the connector when the first portion of the sleeve is removed from the second portion of the sleeve. The second tubing and the third tubing remain attached to the connector when the first portion of the sleeve is removed from the second portion of the sleeve. This feature is neither shown nor suggested by the prior art, including the Dye and Arkans '219 patents. The examiner contends that Arkans 6,062,244 shows a similar feature. Applicants disagree. Arkans '244 discloses an arrangement in which the upstream and downstream connector parts 42, 44 are either connected to permit flow of pressurized fluid through both lines 32a, 32b to the compression device or disconnected to prevent flow through both lines 32a, 32b to the compression device. The connector parts and fluid flow lines cannot be manipulated to allow one line to be disconnected to prevent or inhibit flow to one portion of the compression device while at the same time permitting another line or lines to remain

attached to permit flow to another portion or portions of the compression device, as claimed by applicants.

Third, claim 29 states that the connector comprises a valve for partially closing the quick disconnect port when the first tubing is removed from the connector such that fluid from the pressurized fluid source continues to flow from the port and the sequential compression vascular therapy is able to continue without interruption. As explained above, there is no disclosure or suggestion of applicants' partial closure feature in the prior art cited by the examiner. It will be noted in this regard that disconnection of the connector parts 42, 44 in the '244 Arkans patents results in complete blockage of fluid through the connector parts and fluid flow lines. (See col. 5, lines 46-49.) Partial flow is not permitted.

For at least the above reasons, claim 29 is allowable over the cited art.

Claim 30 depends from claim 29 and is allowable for at least the same reasons as claim 29.

Further, claim 30 states that the connector valve is movable when the first tubing is removed from the connector to reduce fluid flow from the pressurized fluid source through the fluid port to a level approximating flow to the first expandable chamber prior to removal of the first portion of the sleeve from the second portion of the sleeve. This feature is advantageous because it maintains continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations. (See page 12, lines 6-15 of the present application.) There is no disclosure or suggestion of this feature in the prior art cited by the examiner. As noted previously, disconnection of the connector parts 42, 44 in the '244 Arkans patents results in complete blockage of fluid through the connector parts and fluid flow lines. (See col. 5, lines 46-49.) Partial flow is not permitted.

Claim 31 depends from claim 29 and is allowable for the same reasons as claim 29.

In addition, claim 31 states that the first and second portions of the sleeve are connected by a flexible section of reduced width having a knee opening therein, and that the perforations extend across the flexible section at a location below the knee opening. Dye discloses a compression sleeve having a knee opening 16, but Dye does not disclose

applicants' claimed perforations or where such perforations should be located relative to the knee opening (e.g., above the knee opening, below the knee opening, or at some intermediate location). Applicants' claimed location below the knee opening is particularly advantageous because the amount of scrap remaining on the second portion of the sleeve is minimized after the first portion is torn away.

Claim 32 depends from claim 17 and is submitted to be allowable for at least the same reasons as claim 17.

Claim 33 also depends from claim 17 and is submitted to be allowable for the same reasons as claim 17. Further, the claim is amended to state that the first tubing is connected to the thigh and calf portions of the sleeve but is not connected to the ankle portion of the sleeve. This arrangement, which enables securement of the first tubing to the sleeve while also facilitating removal of the thigh portion of the sleeve from the remainder of the sleeve, is not shown or suggested by the prior art of record, including Dye where the thigh tubing 46d is connected to the ankle portion of the sleeve. The examiner contends that not connecting the first tubing to the ankle section would have been obvious in view of Arkans '219. However, Arkans does not teach connecting a first tubing to multiple portions of a sleeve to enhance securement while at the same time not connecting the tubing to another portion of the sleeve to facilitate removal of the tubing.

CONCLUSION

In view of the foregoing, applicants request reconsideration and allowance of claims 1, 3-12, 14-19, 22, 24-26 and 29-33.

The Commissioner is hereby authorized to charge any fees and credit any overpayment to Deposit Account No. 19-0254.

Respectfully submitted,

/Kurt F. James/

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KFJ/dlw

April 12, 2010

Commissioner for Patents  
Attention of Examiner Danton D. Demille  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313

Dear Examiner Demille:

My Background

I am a Registered Nurse in the Intensive Care Unit at Saint Francis Hospital. I have over 12 years of experience in the nursing profession. During that time I have used many compression sleeves in the treatment of my patients.

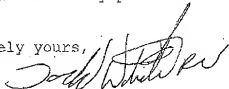
Summary

In particular, compression sleeves are often used to protect the limbs (e.g., leg) of a patient during surgery. Thigh-length sleeves (sleeves extending from the ankle area past the knee to the upper thigh) are typically used during surgery because of their ability to fully cover the leg for protection. Prior to the KAMBIA sleeve (commercial version of the sleeve of the present invention), compression sleeves were not capable of being modified from the thigh-length configuration to the smaller knee-length size (sleeves extending from the ankle area to just below the knee). Accordingly, after surgery was complete, the clinician was forced to either leave the thigh-length sleeve on which can be uncomfortable, or completely replace the thigh-length sleeve with a separate knee-length sleeve which is costly.

It has been my experience that the KAMBIA sleeves provide easy conversion from the thigh-length to the knee-length configuration. I like the KAMBIA sleeve because you get optimum protection during surgery yet still have the ability to rip the sleeve down to the knee-length sleeve to improve comfort post operation. This convenient tear-away feature provides the long overdue advantage of being able to use a single sleeve during and after surgery without compromising protection or comfort. Without question, I would recommend to the board at Saint Francis that they purchase the KAMBIA sleeves because the sleeve's versatility, ease of use and cost saving potential.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,



Todd White, RN  
ICU Nurse  
St. Francis Hospital



June 2<sup>nd</sup>, 2010

Commissioner for Patents  
Attention of Examiner Danton D. Demille  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313

Dear Examiner Demille:

My Background

I am employed by Covidien as Global Product Manager, Compression. I have worked at Covidien for 4-1/2 years. I am responsible for the sale of compression products, including the KAMBIA sleeve (commercial version of the sleeve of the present invention), both domestically and outside the United States.

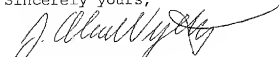
Summary

The KAMBIA sleeve is a commercially successful product. The product was launched globally by Covidien in 2005, and sales have enjoyed a rapid rate of growth, as exemplified by the numbers on the attached spreadsheet. Overall, the sales growth for the KAMBIA product has been greater than would normally be expected for comparable products sold by Covidien.

Based on customer feedback, including the accompanying declaration from ICU nurse Todd White, I believe the commercial success of the KAMBIA sleeve is due its tear-away feature allowing the sleeve to be readily converted from a thigh-length to a knee-length configuration. The tear-away feature improves the sleeve's versatility, ease of use, and cost saving potential.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "J. Wyrzten", with a stylized flourish extending to the right.

Jeffrey Wyrzten  
Global Product Manager, Compression  
Covidien